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(54) **PERCUTANEOUS TRANSSEPTAL LEFT ATRIAL CANNULATION SYSTEM.**

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Description

Background

Circulatory support during coronary bypass surgery, heart transplantation, or after failed coronary angioplasty is currently achieved using cardiopulmonary bypass. This involves the complete support of the heart and lungs by diverting all the blood returning to the heart through a pump and oxygenator, before returning it to the arterial circulation. During coronary artery bypass grafting or heart transplantation, cannulation for cardiopulmonary bypass is done at surgery through the chest, whereas cardiopulmonary bypass for failed coronary angioplasty can be done percutaneously through the groin in the cardiac catherization lab. Regardless of the circumstances or route of cannulation, cardiopulmonary bypass has a time limitation of three to four hours due to the continued trauma to formed blood elements such as platelets and red blood cells. This is primarily due to the oxygenator in the circuit. The patient must undergo full anticoagulation with heparin prior to cardiopulmonary bypass and the bypass circuit must be assembled and run by a certified perfusionist.

Circulatory support before and after surgery may be required for several days. Usually the lungs and right ventricle are functioning adequately and only the left ventricle requires extended support. The employment of left ventricular assist allows extended circulatory support without the blood trauma of cardiopulmonary bypass or the services of a perfusionist and requires only partial anticoagulation.

Left ventricular assist requires the drainage of blood from the left atrium of the heart which is currently done by cannulation of the left atrium at the time of surgery. In 1962, an alternative method called "transseptal left atrial cannulation" was proposed by Dennis et al.. in "Left Atrial Cannulation without Thoracotomy for Total Left Heart Bypass", Aca. Chir. Scand. 123: 267-279, 1962 using a metal cannula directed down the right jugular vein. The cannula was directed across the interatrial septum and drained left atrial blood without the need for thoracotomy. More recently, Glassman et al. in "A method of closed-chest cannulation of the left atrium for left atrial-femoral artery bypass", The Journal of Thoracic and Cardiovascular Surgery, Vol. 69, No. 2, Feb. 1975 has advocated transseptal left atrial cannulation by the right femoral vein. These publications describe hardware and procedures which are too complex and awkward for widespread clinical acceptance.

U.S. Patent No. 4,790,825 issued to Bernstein et al. and considered by the European examiner to represent the closest prior art, illustrates one proposed method of transseptal left atrial cannulation based largely on work with the Glassman group. In Bernstein, first a guide wire protruding through a catheter is inserted into the femoral vein and directs the catheter up the veins to the right atrium. Second, the guide wire is withdrawn from the entire length of the catheter and a needle is directed up the entire length of the catheter and protrudes out the end. The needle pierces the interatrial septum and the catheter is advanced over the needle into the left atrium. Third, the needle is removed from the entire length of the catheter and an obturator (with a circular barb for attaching to the catheter hub) is directed up the entire length of the catheter. Fourth, an external obturator extension is screwed on to the internal obturator. Fifth, a cannula is threaded over the entire length of the catheter and obturator with the tip positioned in the left atrium. Finally, the catheter and the obturator are removed from the interior of the cannula. A thoracotomy is not required for insertion or removal of the left atrial cannula.

Summary of the Invention

The cannulation method of Bernstein is complex. The insertion and removal of the guide wire, the needle, and obturator within the catheter risks potential system movement, dislodgement, inadvertent puncturing of chamber walls, and may compromise system sterility. Valuable time is wasted during the required insertions and removals. Also, if the internal obturator circular barb should malfunction, the catheter cannot be removed from within the cannula. Accordingly, a simpler, quicker, and safer technique for transseptal left atrial cannulation is desirable.

The invention comprises a device for draining blood from the left atrium of the heart by utilizing a cannula and catheter in which a guide wire and a needle assembly are positioned axially. The guide wire and the needle assembly can be extended alternately through the distal catheter orifice. A cannula is positioned over the catheter (and can slide thereover) and is inserted into a blood vessel with the catheter. This axial configuration of all the system elements obviates the need for repeated insertion and withdrawal of the guide wire and the needle. Both the guide wire and needle are initially and throughout the procedure positioned within the catheter close to the catheter orifice and can be alternately advanced. The cannula is also initially moved through the veins with the catheter. Once the cannula has been advanced into the left atrium, the guide wire, needle assembly and the catheter can be easily withdrawn in an integral fashion without the risk of barb malfunction leaving the catheter behind. Thus, left drainage can be accomplished

safely, quickly, and without compromising sterility.

The device is used as the venous cannula in a percutaneous transseptal left atrial cannulation system for a left ventricular assist. In use, the catheter, guide wire, needle assembly, and cannula are coaxially configured and inserted together. The device is inserted into the femoral vein in the groin, the guide wire is extended through the distal catheter orifice, and under fluoroscopic guidance, the guide wire followed by the catheter, needle, and cannula are positioned in the right atrium of the heart. Both the guide wire and needle assembly are long enough to allow a substantial length to extend out of the body at the groin for manipulation even when the distal ends of the guide wire and needle assembly are positioned in the heart. The guide wire is withdrawn into the catheter and remains within the catheter body. The needle assembly is advanced through the catheter orifice to the septum and pierces a hole through the septum into the left atrium. The needle assembly is stiff enough to permit the catheter to advance over it through the septum and into the left atrium. The cannula is then advanced over the catheter through the septum into the left atrium. (Conventional, off the shelf interatrial septal needles are too short and flexible. For example, the conventional Ross and Brockenbrough needles would not be stiff enough to allow the cannula to ride thereover when the needle is positioned in the heart and would not be long enough to allow manipulation through a catheter/cannula coupling assembly.) The guide wire, needle assembly, and catheter are removed as an integral unit, leaving only the cannula with its tip in the left atrium. Oxygenated blood from the left atrium of the heart is drained by this venous cannula and is returned to the body by an arterial cannula after passing through an extra-corporeal pump. Thus, left ventricular assist is accomplished without the need for thoracotomy.

The use of the device is simple, safe, efficient and inexpensive. Insertion and removal of individual system elements is avoided and the surgical procedure of thoracotomy is not required for placement or removal. The time restrictions of conventional cardiopulmonary bypass are removed and full patient anticoagulation is not required for this simple extra-corporeal assist circuit. A certified perfusionist is not required to set up or run this system and the cannulae connect to a simple centrifugal pump which is already available as conventional hospital equipment.

In a preferred embodiment of the invention the cannulation system includes a peel-away sheath assembly comprised of a thin-walled tube with a tapered end which covers a plurality of holes on the side of the end of the cannula. A hub is molded onto the thin-walled tube. The hub and tube are scored so that they can be pulled back from the cannula and peeled away. During the initial stage of insertion of the system into the femoral vein, the sheath prevents the cannula holes fron accumulating particulate fat debris prior to reaching the blood stream. The sheath is pulled back and peeled away after the cannula is within the femoral vein. This ensures no debris will reach the left atrium and possibly cause a stroke.

In a further preferred embodiment, the cannula is coated on both sides with an anti-thrombogenic coating to minimize the potential for blood coagulation on the cannula during long term use.

In yet a further preferred embodiment, the needle assembly includes a metal tube with a narrowed distal end such that a predetermined length of tube can extend out of the catheter orifice but a thicker tube width is stopped at the orifice. The metal tube comprises an inner metal tube which is fixed coaxially within but extends beyond a second outer metal tube. The inner tube has a distal end which is rounded to prevent scraping within the catheter. The inner tube is small enough to pass through the catheter orifice, whereas the outer tube cannot. Thus, the inner tube protrudes only a fixed safe distance from the catheter orifice. A needle wire can be positioned within the inner tube and can be advanced a fixed distance out the distal end of the tube to sharpen the needle. The inner needle lumen also allows aspiration of blood to confirm correct left atrial positioning. The needle assembly is stiff enough to also function as the obturator which holds the catheter rigid during cannula advancement.

The distal end of the needle assembly can be molded into a curve by the operator to assist in directing the needle across the septum. However, under single plane fluoroscopic guidance the needle direction cannot be accurately determined from the screen alone. To confirm the spatial orientation of the curved end of the needle, a hub with a pointer is connected to the proximal end of the needle assembly.

The above and other features of the invention including various novel details of construction and combinations of parts will now be more particularly described with reference to the accompanying drawings and pointed out in the claims. It will be understood that the particular device embodying the invention is shown by way of illustration only and not as a limitation of the invention. The principles and features of this invention may be employed in varied and numerous embodiments without departing from the scope of the invention.

Brief Description of the Drawings

Figure 1(a) illustrates a longitudinal cross-sectional view of the distal end of the cannulation system.

Figure 1(b) shows a side view of the distal end of the cannulation system.

Figure 2(a) illustrates a longitudinal cross-sectional view of the proximal end of the cannulation system.

Figure 2(b) shows a side view of the proximal end of the cannulation system.

Figure 3(a) shows a reducer plug in the system of Figure 2(b).

Figure 3(b) illustrates a cannula hub in the system of Figure 2(b).

Figure 3(c) and 3(d) illustrate side and transverse end views, respectively, of the dual lumen elastic bushing of Figure 2(b).

Figure 3(e) shows a side view of the proximal end of the catheter.

Figure 3(f) shows the proximal end of the guide wire.

Figure 3(g) illustrates a transverse end view of the hub and pointer of the needle assembly proximal end.

Figure 3(h) shows a longitudinal view of the needle assembly proximal end.

Figure 3(i) shows a longitudinal view of the needle wire proximal end.

Figure 4(a) shows the cannula distal end.

Figure 4(b) illustrates the peel-away sheath assembly.

Figure 4(c) shows the catheter distal end.

Figure 4(d) shows the guide wire distal end.

Figure 4(e) shows the needle assembly distal end.

Figure 4(f) shows the needle wire distal end.

Figures 5(a), (b), and (c) illustrate a detailed longitudinal cross-sectional view of the distal assembly with different positions of the guide wire, needle and needle wire.

Figures 6(a), (b), and (c) show the progressive placement of the cannulation system into the heart.

Figure 7 provides a schematic view of the venous cannulation system, pump, and arterial cannula.

Detailed Description of the Preferred Embodiments

Figures 1(a) and (b) illustrate the distal end of the cannulation system. A radio-opaque polyurethane catheter 5 comprising a 80cm [32 inch] long (but can vary in range from 75cm to 87.5cm [30 inches to 35 inches]), 4mm [12 french] tube contains a guide wire 17 and a needle assembly 9, 11, 15 which can alternately be advanced through the orifice 13 as shown in Figure 4(c) in the catheter distal end. The catheter is not preformed, but the assembly can be bent by the physician prior to insertion, and the needle retains the shape and imparts a shape to the catheter as illustrated. The needle has sufficient shape memory, yet is sufficiently flexible to follow the shape of a vein without losing its curve once it moves into the atrium.

As shown in detail in Figures 4(e) and (f) the needle assembly includes a needle wire 9 which is stainless steel, a first metal tube 11 which can advance through the catheter orifice 13 and an outer metal tube 15 which cannot extend through the catheter orifice 13. A single metal tube with a narrowed distal end such that a predetermined length of tube projects out of the catheter orifice but a thicker tube width is stopped at the orifice may be substituted for tubes 11 and 15. The needle assembly comprises two pieces of hypodermic stainless steel tubing of No. 3. temper, held together coaxially by a molded PETG copolyester hub 29. The 0.89mm [20 gauge] outer diameter of the smaller tube is 1.88cm [.75 inches] longer than the 92.5cm [37 inch] long, 1.24cm [18 gauge] larger tube. The stainless steel needle wire 9 is 97.5cm [39 inches] long and 0.38mm [.015 inches] in diameter. (The lengths of the needle assembly components can be shortened by 5cm [2 inches] or lengthened by 7.5cm [3 inches]. The lengths can be any dimension within this range.) The outer tube 15 has a wall thickness of 0.15mm [.006 inch], an outer diameter range of 1.24mm - 1.26mm [.0495 inch - .0505 inch] and an inner diameter range of 0.94mm - 0.99mm [.0375 inch - .0395 inch]. The inner tube 11 has a wall thickness of 0.15mm [.006 inch], an outer diameter range of 0.888mm - 0.900mm [.0355 inch -.0360 inch] and an inner diameter range of 0.575mm - 0.612mm [.0230 inch -.0245 inch]. The smaller inner metal tube fits inside of the outer metal tube. The smaller tube is than the outer tube and protrudes out the end for a fixed distance and has a rounded end to prevent scraping within the catheter 5. At the catheter tapered tip, the inner diameter is reduced to 0.9mm [.036 inch] so that only the 0.9mm [.036 inch] guide wire or only the 0.889mm [20 gauge] needle can fit through the orifice 13. The outer tube 15 cannot fit through the catheter orifice 13 and fixes the distance which the inner tube 11 can extend beyond the catheter orifice 13.

The needle assembly punctures the septum and subsequently acts as a stiff curved guide to direct both the catheter and cannula across the septum and into the left atrium. The needle assembly has a stiffness sufficient to guide the catheter and cannula over it as well as have adequate flexibility to permit passage through the veins enroute to the right atrium. Hypodermic needle stock full hard at the aforementioned gauges is used to

satisfy the stiffness requirements.

The cannula 3 consists of a 60cm [24 inch] (but can vary in range from 55cm to 67.5cm [22 inches to 27 inches]) long 7mm [21 french] radiopaque thin wall polyurethane tube with a tapered tip and side holes 7 at its distal end. The outer diameter for cannula 3 with a 7mm [21 french] tube is 6.9mm [.276 inch]. The cannula 3 tube size can vary from 6mm to 8mm [18 french to 24 french]. The cannula tapered tip slides over the exterior of catheter 5. The catheter 5 has an inner diameter of 2.5mm [.100 inch] and the cannula 3 has an inner diameter of 5.4mm [.216 inch]. The cannula is coated on both sides with an antithrombogenic agent. For example, the cannula may be typically bonded with heparin.

A peel-away sheath assembly is comprised of polypropylene hub 1 which is molded onto a 12.5cm [5 inch] long thin-walled polytetrafluorethylene tube 31 with a tapered end. Both the hub and the tube are scored in such a way that they will tear longitudinally in half and be easily removed from the cannula. The peel-away sheath covers the holes 7 in the cannula 3 during the initial stage of percutaneous insertion when the cannula traverses the subcutaneous fat. It shields the cannula holes from accumulating particulate subcutaneous fat debris prior to reaching the blood stream. Once the cannula is within the femoral vein, the sheath is pulled back and peeled away. Figures 4(a) and 4(b) show the cannula and the peel-away sheath assembly in more detail.

Figures 2(a) and (b) show the cannulation system proximal end. The catheter-cannula coupling assembly 99 is comprised of cannula hub 19, barb tube connector 21, reducer plug 23, male connector 25, bushing holder 49, bushing 47 and closing ring 27. The cannula hub 19 is clear, hollow, and comprised of two polyvinylchloride components 18 and 20. The distal component 20 of hub 19 is flexible and can be clamped. As shown in Figure 3-(b), the cannula hub 19 distal end is fixed to the cannula 3. The cannula hub 19 proximal end is rigid and fixed to a rigid, barbed tube connector 21 which has a standard 9.4mm [3/8 inch] diameter. A reducer plug 23, shown in detail in Figure 3(a), includes a molded polypropylene male tapered connector on its distal end and a female tapered connector on the proximal end. The reducer plug male connector is attached to the tube connector 21. The tube connector 21 is comprised of a proximal component which is attached to the inner portion of a distal component. The reducer plug female connector wraps around the proximal catheter end to minimize blood loss. As shown in Figures 3-(c), (d), and (e), the catheter proximal end includes a polypropylene male connector 25 with a bushing holder 49 including jaws, a dual lumen elastic silicone bushing 47, and a closing ring 27 which provides a friction fit to prevent the guide wire and needle assembly from moving if fixation is desired. The guide wire and the needle assembly are alternately moved axially within the catheter. When properly located, their respective positions are fixed by means of closing ring 27 which clamps both elements.

As shown in Figures 3 (g), (h), and (i), the needle assembly proximal end includes a hub 29 attached to the metal tubes, a pointer 33 for indicating the angular orientation of the curved distal end of the needle assembly, and a molded polypropylene hub 35 attached to the needle wire 9. A single plane fluoroscopic display cannot distinguish the anterior or posterior position of the curved needle distal end. However, when display information is combined with the pointer indication, the needle orientation can be determined. Moreover, the integral configuration of the system allows the protected delivery of the needle assembly to the right atrium of the heart over the guide wire. The guide wire 17 is pulled back and the needle wire 9 and the inner metal tube 11 are advanced to effect the transseptal puncture of the heart. Figure 3(f) shows the guide wire proximal end which is moved to position the guide wire. The guide wire 17 is comprised of a stainless steel spring wire wrapped around a separate core wire. The guide wire 17 is 140 cm long and 9mm [.036 inch] in diameter. The distal end of the wire is more flexible than the center portion. The guide wire is preformed and has hysteresis to assume a curved shape when extended out of the catheter to prevent catching of the wire on venous side branches, as shown by Figure 4(d). The guide wire guides the catheter to the right atrium and once the catheter is in the left atrium it can be used to assess the distance to the lateral left atrial wall. It can also be used to deflect and foreshorten the catheter tip to minimize the risk of damaging the wall of the left atrium after the catheter has advanced through the septum.

Figures 5(a), (b) and (c) illustrate the operation of the catheter elements. The catheter curvature results from conforming to the preformed needle curve. Figure 5(a) shows guide wire 17 extended in a curled configuration to facilitate guiding the catheter through the venous system. Figure 5(b) shows the withdrawn guide wire and extended inner metal tube 11 of the needle assembly. Figure 5(c) shows the needle wire 9 extended through the inner metal tube 11 to sharpen the needle assembly.

Figures 6(a), (b), (c) illustrate the steps in positioning of the inventive system in the heart. The cannulation system is inserted into the femoral vein using a conventional breakaway Seldinger needle through which guide wire 17 is threaded. The transseptal cannulation system is advanced over guide

wire 17 into the femoral vein. Both the guide wire and needle are long enough to allow a substantial length to extend out of the body at the groin for manipulation even when the distal ends of the guide wire and needle are positioned in the heart. Thus, the cannula can be easily loaded thereover and carried therewith through the vein. Once the cannula holes 7 pass into the blood stream, the sheath 1, 31 is pulled back and peeled away. The guide wire 17 assists in guiding the cannulation system to the right atrium of the heart under fluoroscopic guidance. Once the catheter is in the right atrium with the cannula at the level of the diaphragm, the guide wire is withdrawn into the catheter and the needle assembly is advanced to the septum. Figure 6(a) shows this position where the curved end of the needle-catheter is touching the septum. The curved needle is dragged down the interatrial system into the fossa ovalis area of the septum. A ridge surrounds this region and provides a tactile and visual indication of falling into the fossa. The tube 11 is oriented 45° dorsally. The fluoroscopic display of the needle tip and the hub pointer on the needle assembly provide confirmation of proper orientation. When the needle is properly positioned, the needle wire 9 is advanced and the septum is pierced.

Figure 6(b) shows the subsequent dilation of the septal hole as the catheter is advanced over the needle assembly. Figure 6(c) shows the further dilation of the septal hole as the cannula enters the left atrium. The appearance of red oxygenated blood from the left atrium in the cannula indicates the tip of the cannula is in the left atrium. The fluoroscopic display provides an indication of the actual cannula location. As an option, the needle wire 9 can be removed from the metal tubes and a radio-opaque dye injected to further confirm the location of the cannula. Also, the curved end of the guide wire can be advanced and observed under fluoroscopy to determine the distance to the lateral left atrial wall. When the cannula is properly positioned, the guide wire, needle assembly and catheter are withdrawn and removed.

Figure 7 shows the complete left ventricular assist system. Oxygenated blood from the left atrium drains through the venous cannula 3 to pump 37. A centrifugal pump which can pump blood safely for several days is shown. However, any conventional pump can be used. For example, a roller pump can also be used in the system. The blood is returned to the body by means of an arterial cannula 41 inserted into the femoral artery.

Possible clinical applications of the invention include three separate aspects of adult cardiac care. First, during coronary angioplasty, there is a risk of unexpected coronary artery damage resulting in hemodynamic collapse. If the patient was known to be high risk prior to the angioplasty procedure, a conventional guide wire could be positioned across the interatrial septum prior to the angioplasty. This device, with its guide wire removed, could then be inserted over the prepositioned guide wire for left ventricular assist if a significant problem developed during the procedure. If the problem was completely unanticipated, however, the percutaneous transseptal left atrial cannula atrial system would include all the elements necessary to achieve expeditious transseptal left atrial cannulation and facilitate left ventricular assist.

Secondly, in centers that have an active cardiac transplant program, many patients develop severe cardiac failure while waiting for a heart donor. Mild to moderate cardiac failure can be managed with medications and an intra-aortic balloon pump. However, severe cardiac failure requires some form of left ventricular assist. Although surgically implantable devices are available at a number of centers, arrangements for their insertion is often complex and involves many delays. A number of centers also do not have access to any implantable technology despite having an active cardiac transplant program. This invention would allow left atrial drainage without thoracotomy and the establishment of left ventricular assist using universally available centrifugal pumps while arrangements were made either for surgical insertion of a more permanent implantable device or while a donor heart was found.

Finally, this device could be considered for post-cardiotomy left ventricular assist by inserting the device in the operating room after heart surgery. In this setting, the patient may have failed to separate from the heart-lung machine and will require several days of temporary left ventricular assist. Insertion in this setting need not be under fluoroscopic control but could be directed by the surgeon through the groin to the heart. The needle assembly and catheter could be directed across the septum by feeling the cannula through the wall of the right atrium while still on cardiopulmonary bypass. The advantage of this approach over direct surgical cannulation of the heart would be that the chest would not have to be reopened several days later when the system was ready to be removed. The risk of bleeding around surgical cannulation sites would be eliminated and the risk of postoperative mediastinal infection would be reduced.

Equivalents

Those skilled in the art will recognize, or be able to ascertain, using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein.

Claims

1. A cannulation system for draining blood from the left atrium of the heart through a blood vessel comprising as an assembly to be inserted through the blood vessel:

   a catheter (5) having a distal end and a proximal end, said distal end including an orifice (13) and an axial cavity;

   a cannula (3) which surrounds the catheter;

   a guide wire (17);

   a needle (9); characterized in that, the cavity width is reduced at the orifice; in that

   the said guide wire and said needle located axially in the catheter such that either the guide wire or the needle can alternately be extended through the orifice at the catheter distal end; and in that

   the needle has a stiffness such that the catheter and cannula can be passed over the needle and through the atrial septum, but is flexible enough to pass through a blood vessel.

2. A cannulation system as recited in Claim 1, wherein the distal end of the cannula has a hole (7) located transverse to the longitudinal axis of the cannula such that the transverse hole of the cannula slides over the exterior of the catheter.

3. A cannulation system, as recited in Claim 1 or 2, further comprising:

   a flexible, hollow cannula hub (19) with a distal end and a proximal end;

   said cannula hub distal end being clampable such that blood in the cannula (3) will not pass through the cannula hub proximal end.

4. A cannulation system, as recited in Claim 3, further comprising:

   a hollow reducer plug (23) with a distal end and a proximal end;

   said reducer plug distal end being connected to said cannula hub (19) proximal end; and

   said reducer plug proximal end surrounding said catheter proximal end, the interior diameter of the reducer plug being smaller than the interior diameter of the cannula hub.

5. A cannulation system, as recited in Claim 4, in which the catheter (5) proximal end further comprises:

   a male connector (25) with a distal end and a proximal end, said male connector distal end being coupled to said reducer plug (23) proximal end;

   a dual lumen elastic bushing (47) which is positioned in the male connector proximal end; said bushing holding the guide wire (17) and the needle (9), said male connector proximal end including a holder (49) for the bushing; and

   a closing ring (27) positioned at the male connector proximal end such that a friction fit prevents the guide wire and the needle from moving in the catheter axially if desired.

6. A cannulation system, as recited in any of Claims 2-5, further comprising:

   a plurality of holes (7) on the side of said cannula (3);

   a peel-away sheath assembly including a thin-walled tube with a tapered end which covers the plurality of holes on the side of the cannula,

   said tube being scored such that it can be pulled back from the cannula and peeled away.

7. A cannulation system, as recited in any preceding Claim, further comprising a guide wire (17) and needle length (9) which are long enough to allow a substantial length to extend out of the body at the groin for manipulation even when the distal ends of the guide wire and needle are positioned in the heart.

8. A cannulation system, as recited in any preceding Claim, in which the needle (9) further comprises a metal tube with a narrowed distal end such that a predetermined length of tube can extend out of the catheter orifice but a thicker tube width is stopped at the orifice.

9. A cannulation system, as recited in Claim 8, in which the tube further comprises an inner metal tube (11) and an outer metal tube (15), such that the inner metal tube is longer and narrower than the outer metal tube and a molded hub which joins the inner and outer metal tubes coaxially, said inner metal tube having a distal end which is rounded to prevent scraping within the catheter (5), said inner metal tube (11) being of a diameter to pass through the catheter orifice (13), said outer metal tube (15) being of a diameter such that it cannot pass through the catheter orifice such that the inner metal tube cannot protrude beyond a fixed distance from the catheter orifice.

10. A cannulation system, as recited in Claim 9, in which said inner (11) and outer (15) metal tubes have a proximal end, said tube proximal end further comprising a hub (29) with a pointer (33) such that the angular orientation of the

pointer indicates the spatial orientation of the curved distal end of the needle (9).

11. A cannulation system, as recited in any preceding Claim, in which the distal end of the needle (9) may be preformed to a curve by the operator.

Patentansprüche

1. Kanülisierungssystem zur Drainage von Blut aus dem linken Vorhof des Herzens durch eine Blutbahn, das als eine durch die Blutbahn einzuführende Anordnung umfaßt:
einen Katheder (5) mit einem distalen Ende und einem proximalen Ende, wobei das distale Ende eine Öffnung (13) und einen axialen Hohlraum enthält;
eine Kanüle (3), die den Katheder umgibt;
einen Führungsdraht (17);
eine Nadel (9), dadurch gekennzeichnet, daß die Hohlraumweite an der Öffnung reduziert ist; daß der Führungsdroht und die Nadel axial in dem Katheder angeordnet sind, so daß sowohl der Führungsdraht als auch die Nadel wechselweise durch die Öffnung an dem distalen Ende des Katheders hervorragen kann;
und daß die Nadel eine Steifigkeit hat, so daß der Katheder und die Kanüle über die Nadel und durch die atriale Scheidewand passieren können, aber flexibel genug ist, um durch die Blutbahn zu führen.

2. Kanülisierungssystem nach Anspruch 1, in welchem das distale Ende der Kanüle ein Loch (7) aufweist, welches quer zur Längsachse der Kanüle angeordnet ist, so daß das Querloch der Kanüle über das Äußere des Katheders gleiten kann.

3. Kanülisierungssystem nach Anspruch 1 oder 2 desweiteren mit:
einer flexiblen, hohlen Kanülenhülse (19) mit einem distalen Ende und einem proximalen Ende;
wobei das distale Ende der Kanülenhülse festklemmbar ist, so daß das Blut in der Kanüle (3) nicht durch das proximale Ende der Kanülenhülse fließt.

4. Kanülisierungssystem nach Anspruch 3 desweiteren mit:
einem hohlen Reduzierkolben (23) mit einem distalen Ende und einem proximalen Ende;
wobei das distale Ende des Reduzierkolbens mit dem proximalen Ende der Kanülenhülse (19) verbunden ist; und
das proximale Ende des Reduzierkolbens das proximale Ende des Katheders umgibt, wobei der innere Durchmesser des Reduzierkolbens kleiner als der innere Durchmesser der Kanülenhülse ist.

5. Kanülisierungssystem nach Anspruch 4, in welchem das proximale Ende des Katheders (5) weiter umfaßt:
ein männliches Verbindungsstück (25) mit einem distalen Ende und einem proximalen Ende, wobei das distale Ende des männlichen Verbindungsstücks an das proximale Ende des Reduzierkolbens (23) gekoppelt ist;
eine duallumen elastische Buchse (47), die in dem proximalen Ende des männlichen Verbindungsstücks positioniert ist;
wobei die Buchse den Führungsdraht (17) und die Nadel (9) trägt, und das proximale Ende des männliche Verbindungsstücks einen Halter (49) für die Buchse enthält;
und einen Verschlußring (27), der an dem proximalen Ende des männlichen Verbindungsstücks positioniert ist, so daß ein Reibschluß den Führungsdraht und die Nadel hindert sich axial in dem Katheder zu bewegen, wenn dies gewünscht wird.

6. Kanülisierungssystem nach einem der Ansprüche 2-5 desweiteren mit:
mehreren Löchern (7) an der Seite der Kanüle (3);
einer abstreifbaren Hüllenanordnung, welche ein dünnwandiges Rohr mit einem verjüngten Ende enthält, das die mehreren Löcher an der Seite der Kanüle abdeckt, wobei das Rohr so gekerbt ist, daß es von der Kanüle zurückgezogen und abgestreift werden kann.

7. Kanülisierungssystem nach einem der vorstehenden Ansprüche desweiteren mit einer Führungsdraht- (17) und Nadellänge (9), die lang genug sind, um eine ausreichende sich aus dem Körper an der Leistengegend erstreckende Länge zur Manipulation zu ermöglichen, auch dann wenn die distalen Enden des Führungsdrahts und der Nadel in dem Herzen positioniert sind.

8. Kanülisierungssystem nach einem der vorstehenden Ansprüche, in welchem die Nadel (9) weiter ein Metallrohr mit einem engen distalen Ende umfaßt, so daß eine vorbestimmte Länge des Rohres aus der Kathederöffnung hervorragen kann, aber ein dickers Rohr an der Öffnung aufgehalten wird.

9. Kanülisierungssystem nach dem Anspruch 8, in welchem das Rohr weiter ein inneres Metall-

rohr (11) und ein äußeres Metallrohr (15) umfaßt, so daß das innere Metallrohr länger und enger als das äußere Metallrohr ist und eine geformte die inneren und äußeren Metallrohre koaxial verbindende Hülse, wobei das innere Metallrohr ein distales Ende aufweist, welches abgerundet ist, damit es nicht innerhalb des Katheders (5) schabt, und das innere Metallrohr (11) einen Durchmesser hat, der durch die Katheteröffnung (13) paßt, wobei das äußere Metallrohr (15) einen Durchmesser hat, daß es nicht durch die Katheteröffnung paßt, so daß das innere Metallrohr nicht über einen festen Abstand hinaus aus der Katheteröffnung hervorragen kann.

10. Kanülisierungssystem nach dem Anspruch 9, in welchem das innere (11) und das äußere (15) Metallrohr ein proximales Ende haben, welches weiter eine Hülse (29) mit einem Zeiger (33) umfaßt, so daß die gewinkelte Orientierung des Zeigers die räumliche Orientierung des gekrümmten distalen Endes der Nadel (9) anzeigt.

11. Kanülisierungssystem nach einem der vorstehenden Ansprüche, in welchem das distale Ende der Nadel (9) durch den Operateur in eine Krümmung geformt werden kann.

Revendications

1. Système de canulation pour le drainage du sang de l'oreillette gauche du coeur via un vaisseau sanguin comprenant un ensemble destiné à être inséré dans le vaisseau sanguin comprenant :

un cathéter (5) ayant une extrémité distale et une extrémité proximale, ladite extrémité distale comportant un orifice (13), et une cavité axiale ;

une canule (3) enfilée sur le cathéter ;

un fil de guidage (17) ;

une aiguille (9) ; caractérisé en ce que la largeur de la cavité est réduit à son orifice ; en ce que

ledit fil de guidage et ladite aiguille situées axialement dans le cathéter de façon à ce que le fil de guidage ou l'aiguille puissent être alternativement avancés par l'orifice situé à l'extrémité distale du cathéter ; et en ce que

l'aiguille présente une rigidité telle que le cathéter et la canule peuvent être enfilés sur l'aiguille et poussés au-delà du septum interauriculaire, et une flexibilité suffisante pour progresser dans un vaisseau sanguin.

2. Système de canulation selon la revendication 1, dans lequel l'extrémité distale de la canule comporte un orifice (7) situé transversalement par rapport à l'axe longitudinal de la canule de sorte que l'orifice transversal de la canule coulisse sur l'extérieur du cathéter.

3. Système de canulation selon la revendication 1 ou 2, comprenant en outre :

une garde de canule flexible et creuse (19) comportant une extrémité distale et une extrémité proximale ;

ladite extrémité distale de la garde de canule étant verrouillable de façon à ce que le sang dans la canule (3) ne parvienne pas jusqu'à l'extrémité proximale de la garde de canule.

4. Système de canulation selon la revendication 3, comprenant en outre :

un bouchon réducteur creux (23) ayant une extrémité distale et une extrémité proximale ;

ladite extrémité distale du bouchon réducteur étant reliée à ladite garde de canule (19) ; et

ladite extrémité maximale du bouchon réducteur (23) entourant ladite extrémité proximale du cathéter, le diamètre interne du bouchon réducteur étant plus petit que le diamètre interne de la garde de canule.

5. Système de canulation selon la revendication 4, dans lequel l'extrémité proximale du cathéter (5) comprend en outre :

un connecteur mâle (25) ayant une extrémité distale et une extrémité proximale, ladite extrémité distale du connecteur mâle étant couplée à ladite extrémité proximale du bouchon réducteur (23) ;

une douille élastique à double lumière (47) qui est positionnée dans l'extrémité proximale du connecteur mâle ; ladite douille maintenant le fil de guidage (17) et l'aiguille (9), ladite extrémité proximale du connecteur mâle comprenant un support (49) de douille ; et

un anneau de fermeture (27) positionné à l'extrémité proximale du connecteur mâle de façon à ce qu'une connexion par friction empêche, si nécessaire, tout mouvement du fil de guidage et de l'aiguille dans le cathéter dans le sens axial.

6. Système de canulation selon l'une des revendications 2 à 5, comprenant en outre :

une pluralité d'orifices (7) sur le côté de ladite canule (3) ;

un ensemble formant gaine pelable com-

prenant un tube à paroi mince ayant une extrémité conique qui couvre la pluralité d'orifices situés sur le côté de la canule,

ledit tube étant rainuré de façon à pouvoir être décollé de la canule et retiré.

7. Système de canulation selon l'une des revendications précédentes, comprenant en outre un fil de guidage (17) et une aiguille (9) de longueur suffisante pour permettre à une longueur substantielle de dépasser du corps au niveau de l'aine en vue de manipulations, même lorsque les extrémités distales du fil de guidage et de l'aiguille sont introduites dans le coeur.

8. Système de canulation selon l'une des revendications précédentes, dans lequel l'aiguille (9) comprend en outre un tube métallique ayant une extrémité distale effilée de telle sorte qu'une longueur prédéterminée de tube peut dépasser de l'orifice du cathéter mais qu'une largeur de tube plus importante est stoppée à l'orifice.

9. Système de canulation selon la revendication 8, dans lequel le tube comprend en outre un tube métallique interne (11) et un tube métallique externe (15), de façon à ce que le tube métallique interne soit plus long et plus mince que le tube métallique externe, et une garde moulée qui réunit coaxialement les tubes métalliques interne et externe, ledit tube métallique interne ayant une extrémité distale arrondie pour éviter de racler l'intérieur du cathéter (5), ledit tube métallique interne (11) étant d'un diamètre qui lui permet de passer dans l'orifice (13) du cathéter, ledit tube métallique externe (15) étant d'un diamètre tel qu'il ne peut franchir l'orifice du cathéter, de sorte que le tube métallique interne ne peut se projeter au-delà d'une distance fixée de l'orifice du cathéter.

10. Système de canulation selon la revendication 9, dans lequel ledit tube métallique interne (11) et ledit tube métallique externe (15) comportent une extrémité proximale, ladite extrémité proximale du tube comprenant en outre une garde (29) munie d'un indicateur (33) de façon à ce que l'orientation angulaire de l'indicateur indique l'orientation spatiale de l'extrémité distale courbe de l'aiguille (9).

11. Système de canulation selon l'une des revendications précédentes, dans lequel l'extrémité distale de l'aiguille (9) peut être préformée en une courbe par l'opérateur.

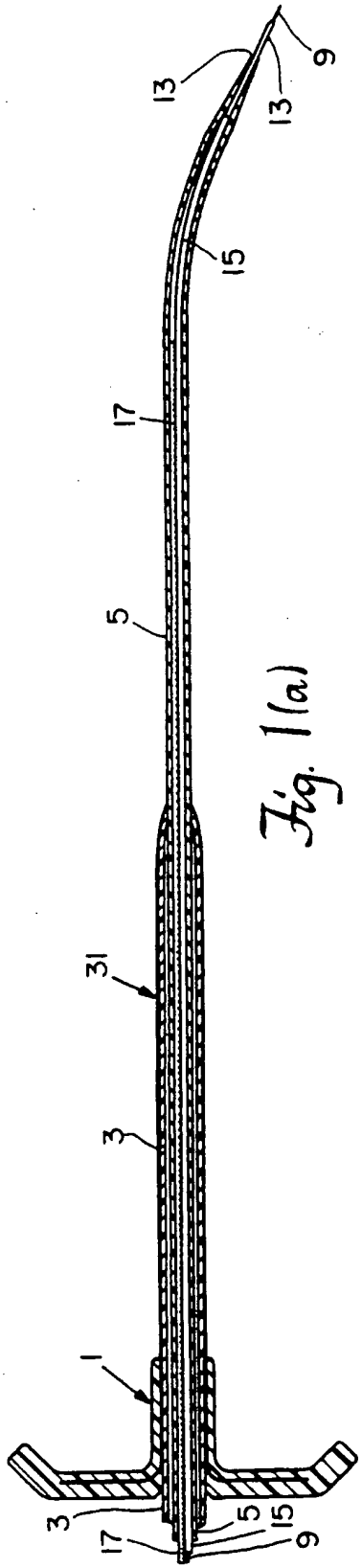

Fig. 1(a)

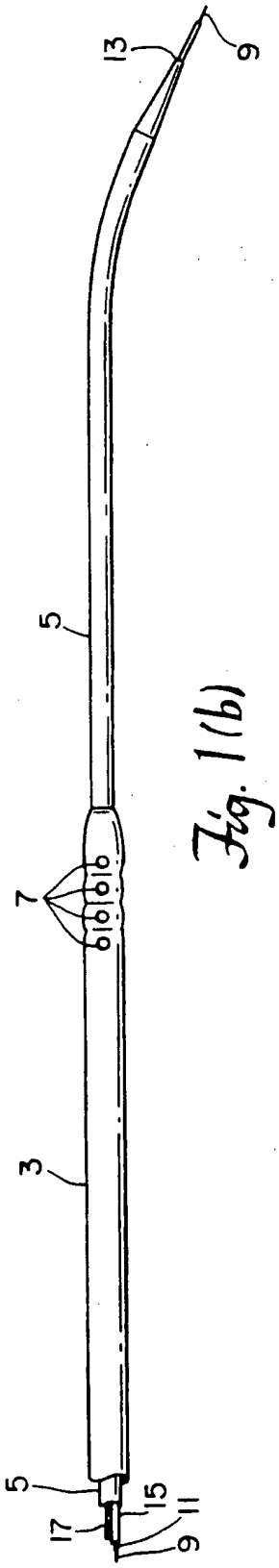

Fig. 1(b)

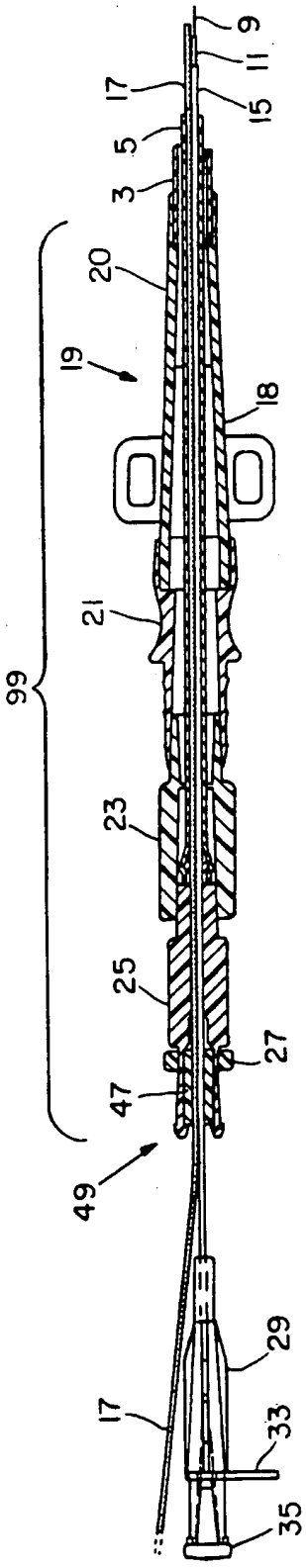
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Fig. 2(a)

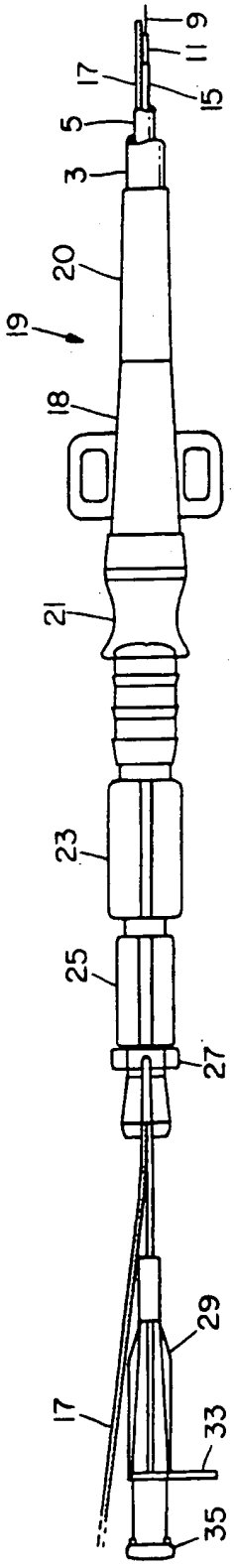
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Fig. 2(b)

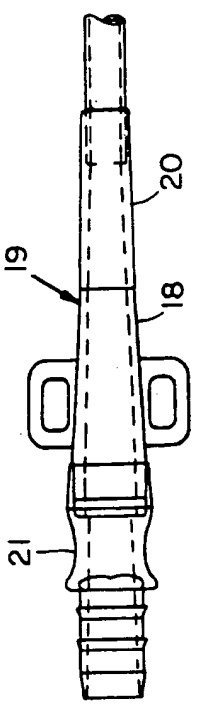


Fig. 3(a)

Fig. 3(b)

Fig. 3(d)

Fig. 3(c)

Fig. 3(e)

Fig. 3(f)

Fig. 3(h)

Fig. 3(i)

Fig. 3(g)

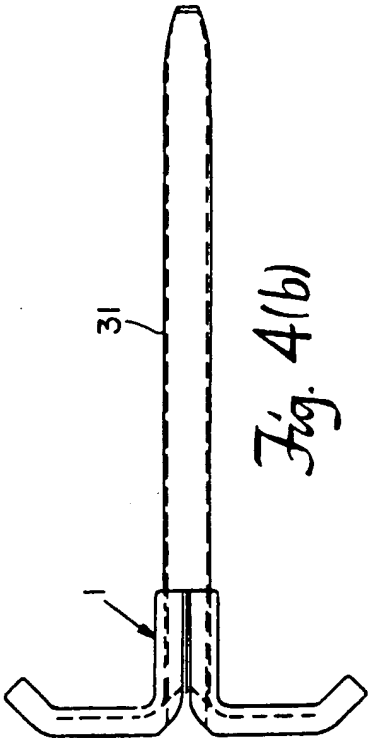


Fig. 4(b)

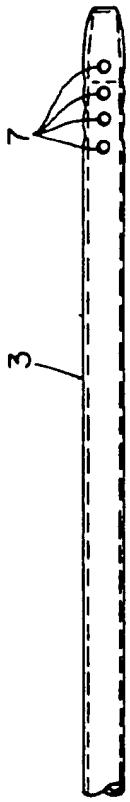
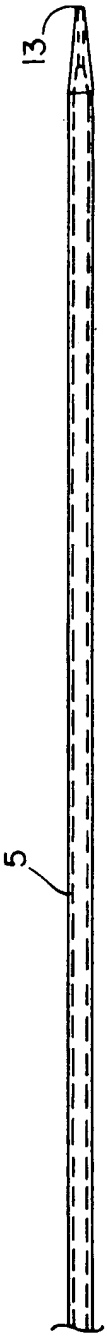


Fig. 4(a)



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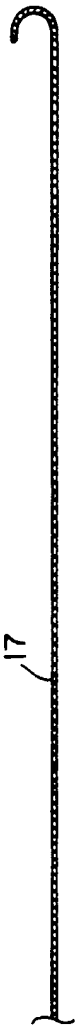

Fig. 4(d)

Fig. 4(e)

Fig. 4(f)

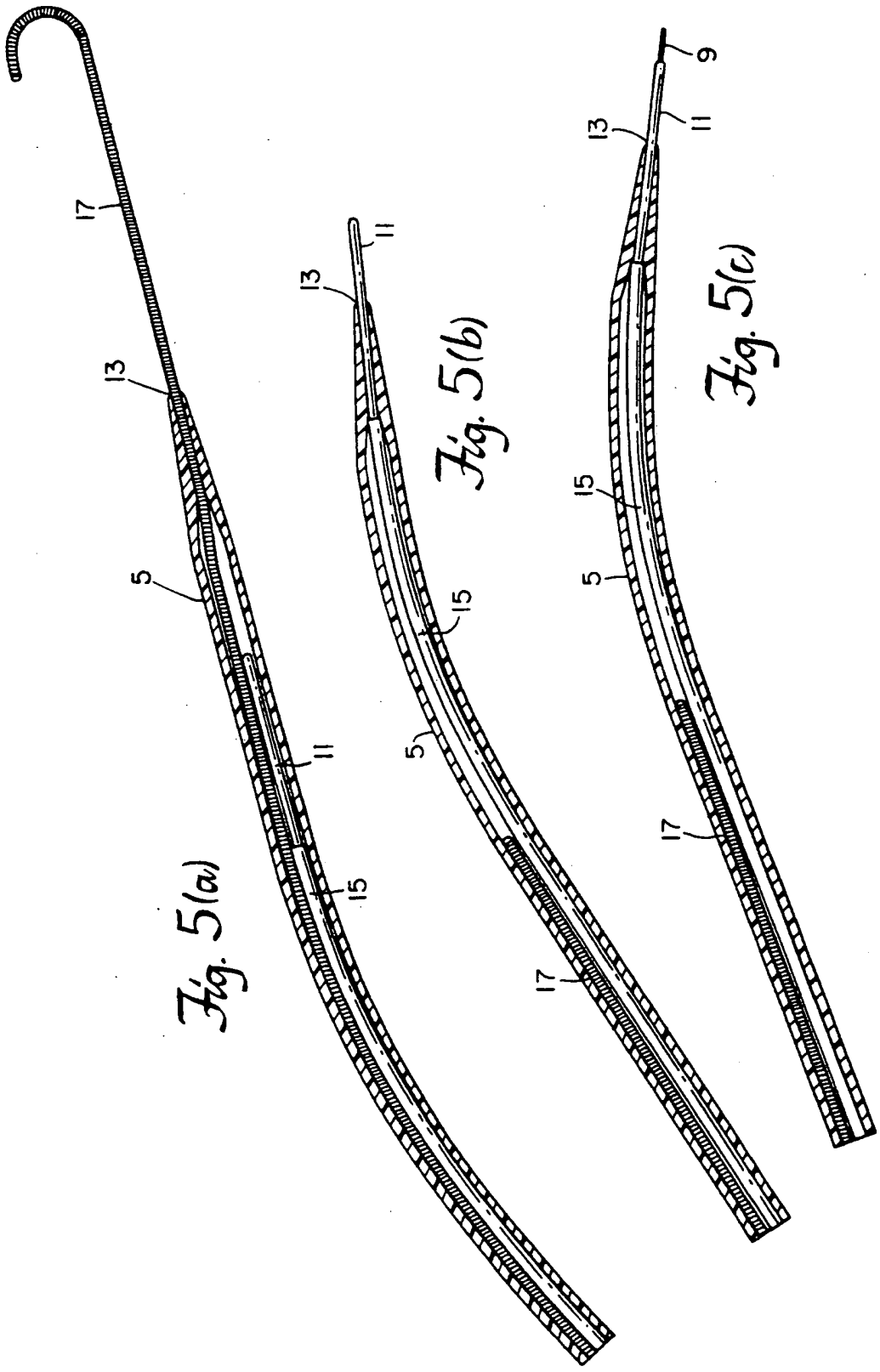
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Fig. 5(a)
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Fig. 5(b)
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Fig. 5(c)

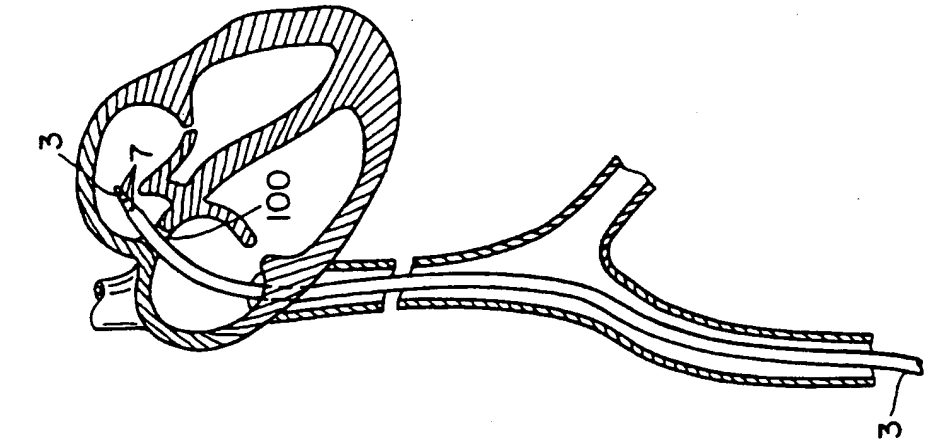

Fig. 6(c)

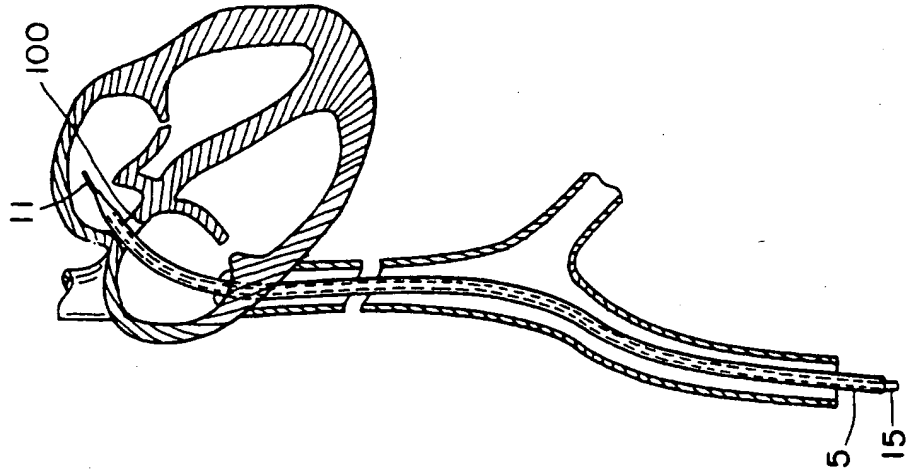

Fig. 6(b)

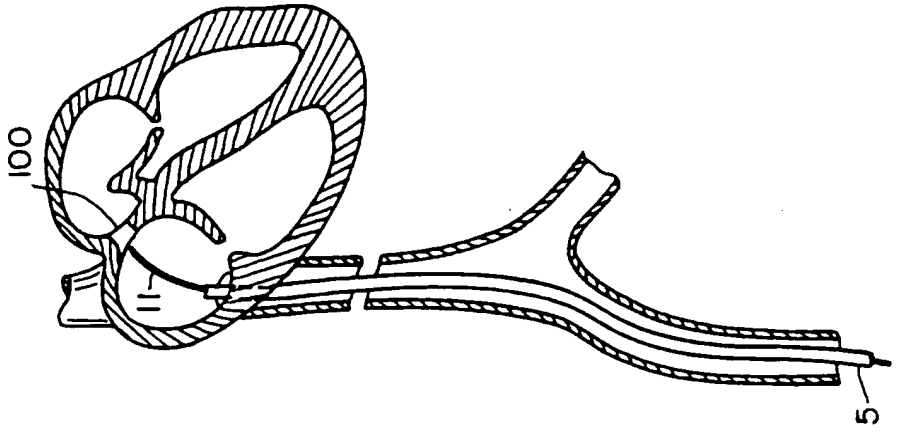

Fig. 6(a)

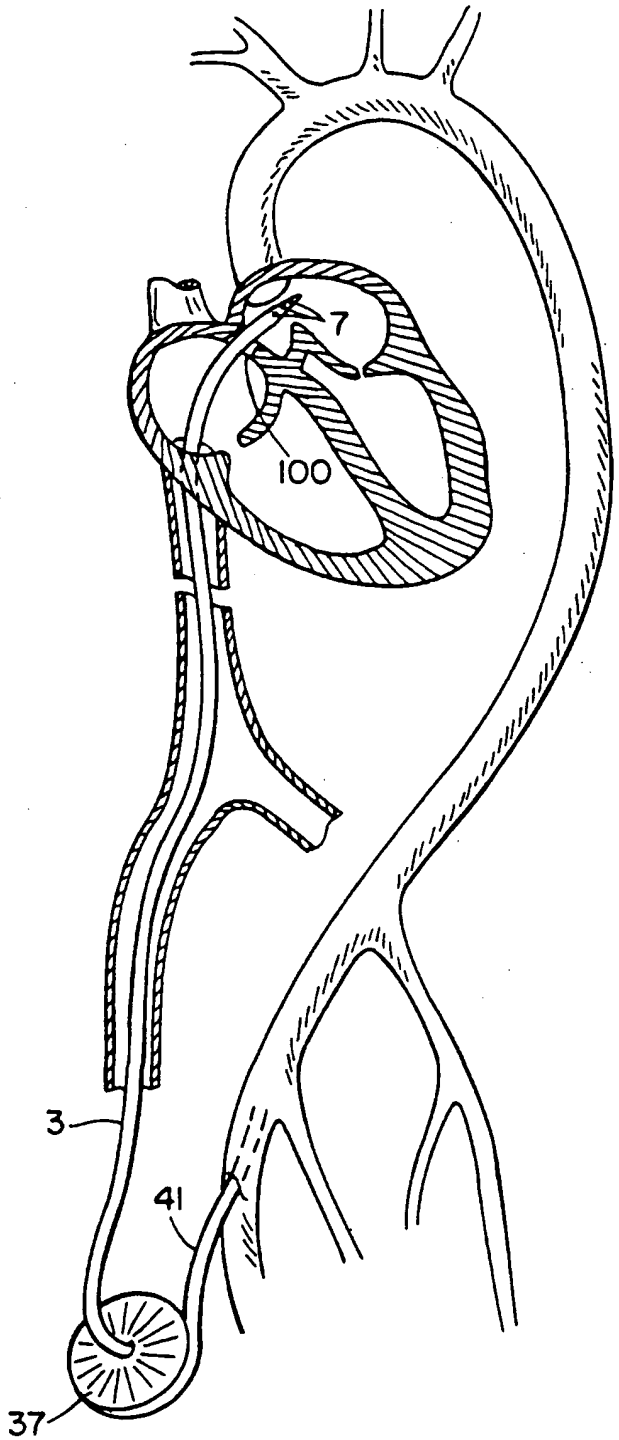

Fig. 7